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March 18, 1999

BY HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

Re: Docket No.: 97N-0314; Levothyroxine Sodium Prescription Drug Products

Dear Food and Drug Administration:

This comment is submitted by Jones Pharma Incorporated (Jones), in partial support of the September 25, 1998 citizen petition submitted by Knoll Pharmaceutical Company (Knoll) to this docket, item number CP 3. Jones manufactures and distributes the prescription drug product Levoxyl®, containing the active ingredient levothyroxine sodium.

* * *

The agency's August 14, 1997 Federal Register notice states that FDA will permit orally administered levothyroxine prescription drug products to be marketed without approved new drug applications (NDAs) only until August 14, 2000. After August 14, 2000, Jones urges the agency to exercise its enforcement discretion and refrain from taking enforcement action against any currently marketed products that are the subject of pending NDAs submitted to FDA and accepted for filing before August 14, 2000, unless the agency concludes that a particular sponsor's NDA is not approvable and is unlikely to become approvable. This approach is clearly within the scope of the agency's enforcement discretion. See 21 U.S.C. § 336; Heckler v. Chaney, 470 U.S. 821 (1985); Cutler v. Kennedy, 475 F. Supp. 838 (D.D.C. 1979). FDA has taken a similar approach in the number of instances. See e.g., 21 C.F.R. § 558.15 (1998) (permitting the continued marketing of antibiotics for animal feed use) and 49 Fed. Reg. 25,681 (June 22, 1984) (permitting the continued marketing of the drug dicyclomine hydrochloride). This relief is generally consistent with much of the relief sought by Knoll.

* * *

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Based on meetings with the review staff and management of the Center for Drug Evaluation and Research, it appears that the agency is taking the view that it will refuse to accept any more 505(b)(2) NDAs after the first 505(b)(2) NDA has been approved. While any 505(b)(2) applications pending at the time the first 505(b)(2) NDA is approved will continue to be reviewed, any later submissions would have to be either full 505(b)(1) NDAs or abbreviated new drug applications (ANDAs). See May 18, 1998 letter from King & Spalding to Dr. Solomon Sobel, enclosure to item number LET 3 in this docket, and Knoll citizen petition CP 3 at 3, n. 7.

Jones agrees with the Knoll petition, that this approach is unlawful and contrary to the terms of the Federal Food, Drug, and Cosmetic Act. The agency's contemplated approach would, in essence, create a race among levothyroxine manufacturers to submit 505(b)(2) NDAs before FDA approves the first 505(b)(2) application. An agency decision not to accept any 505(b)(2) NDAs after approval of the first 505(b)(2) NDA would have the effect of penalizing those levothyroxine manufacturers that took a longer time to formulate a high quality, stable drug product with no stability overage, and to conduct the testing needed to support 505(b)(2) NDA approval. If such a levothyroxine manufacturer were unable to submit its 505(b)(2) NDA before the first 505(b)(2) approval for a competitor -- a situation over which the manufacturer would have no control -- its application would be delayed. The firm would either have to submit a full 505(b)(1) NDA -- a highly unlikely scenario -- or comply with ANDA requirements, including the requirement for a bioequivalency study comparing its product with the reference listed drug. From a public health perspective, this scenario is untenable because it could lead to a shortage of levothyroxine drug products. It could easily lead to a situation in which there is no competition in the levothyroxine drug market for a period of time, thereby in all likelihood leading to higher prices for consumers, taxpayers, and third party payors. Thus, this procedure would penalize -- not reward -- the development of a quality product and would not lead to a level playing field.

* * *

For these reasons, Jones urges FDA to exercise its enforcement discretion and refrain from taking enforcement action against currently marketed products that are the subject of timely submitted NDAs. Moreover, FDA must continue to follow the procedure set forth in its August 14, 1997 Federal Register notice and review all 505(b)(2) NDAs as such, rather than requiring that later submitted applications be converted into full 505(b)(1) NDAs or ANDAs.

Jones appreciates this opportunity to comment.

Respectfully submitted,

David F. Weeda
Arthur Y. Tsien
Counsel to Jones Pharma Incorporated

OFW:cr
cc: Dr. Solomon Sobel